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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|----------------------|---------------------|------------------|
| 09/687,281 | 10/13/2000 | Hyun Kim | GI 5387 | 9127 |

7590 08/01/2003

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WASHINGTON, DC 20005-3315

| EXAMINER |
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WEBER, JON P

| ART UNIT | PAPER NUMBER |
|----------|--------------|
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1651

DATE MAILED: 08/01/2003

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application N .

09/687,281

Applicant(s)

KIM ET AL.

Examiner

Jon P Weber, Ph.D.

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 04 June 2003.
- 2a) ☒ This action is FINAL. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-7 and 11 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-7 and 11 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ 6) ☐ Other: _____

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Status of the Claims

The response with Kim Declaration filed 04 June 2003 has been received and entered.

Claims 1-7 and 11 have been presented for examination.

Claim Rejections - 35 USC § 103

Claims 1-5, 7 and 11 stand rejected under 35 U.S.C. 103(a) as being unpatentable over Valentini et al. (US 5,939,974).

Claim 6 stands rejected under 35 U.S.C. 103(a) as being unpatentable over Valentini et al. (US 5,939,974) in view of Wozney et al. (US 6,187,742).

It is again argued and the Kim Declaration cited in support that the intermediate thick slurry solution of Valentini et al. is not injectable. It is further urged that Valentini et al. do not suggest making the solution injectable. It is further asserted that the solution of Valentini et al. is not pharmaceutically acceptable and does not comprise osteogenic proteins, BMPs.

It is urged that Wozney et al. do not remedy the deficiencies of Valentini et al. above. Further it is urged that Wozney et al. do not use the instant hyaluronic acid derivatives, but rather hyaluronic acid.

The Declaration of Kim asserts that the liquid intermediate of Valentini is not injectable because it requires a porosity of 60-90% (paragraph 10). This is not agreed. Liquids do not have porosity, solids do. The porosity discussed in Valentini is the final product that results from curing the liquid intermediate.

Kim further urges that the large amount of pore former (pre-sieved NaCl crystals according to Valentini) and their size 106-600 microns poses a problem for injectability such that

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the solution could not be injectable. As previously argued, even a thick paste is injectable given 1) a larger needle, and 2) a means to force the paste through the needle. The latter is readily accomplished by a device like a caulking gun.

Accordingly, it is maintained that the intermediate solution of Valentini is injectable. It is noted that the instant injectable compositions are intended to be gels or pastes (page 3, line 23).

The main argument of the response is that Valentini does not teach an injectable solution and that there is no remedy for this deficiency. As seen above, there is no such deficiency. The solution is injectable. As far as the solutions not being pharmaceutically acceptable, it is clear throughout the disclosure of Valentini that the solutions are intended to be used in the body and must necessarily be pharmaceutically acceptable. At column 6, lines 63, to column 7, line 21, the BMPs may be combined with the Hyaff prior to scaffold formation.

At pages 3-4 of the instant disclosure, the instant carrier is a solubilized Hyaff solid (partial esters of hyaluronic acid, e.g., benzyl) and described more completely in Example 1. No particular advantage is asserted for a particular formulation.

The carriers in Wozney et al. do not specifically include hyaluronic acid esters. However, Wozney et al. indicate that a wide range of suitable carriers may be used (column 4, line 17 to column 5, line 57) including hyaluronic acid where it is preferred that the mixture of carrier and BMP is in the form of a viscous gel. The fact that Wozney et al. place only limited emphasis on the carrier provides sufficient motivation to substitute one BMP for another in the instant carriers. It is important to recognize that Wozney et al. is not cited to remedy a deficiency in the carrier, but the particular BMP-7.

Applicant's arguments filed 04 June 2003 have been fully considered but they are not persuasive. The rejections under 35 U.S.C. 103 are adhered to for the reasons of record and the additional reasons above.

No claims are allowed.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

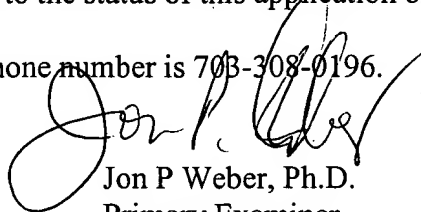
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jon P Weber, Ph.D. whose telephone number is 703-308-4015. The examiner can normally be reached on daily, off 1st Fri, 9/5/4.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael G. Wityshyn can be reached on 703-308-4743. The fax phone numbers for

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the organization where this application or proceeding is assigned are 703-872-9306 for regular communications and 703-872-9307 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

A handwritten signature in black ink, appearing to read "Jon P. Weber", is written over the printed name and title.

Jon P Weber, Ph.D.
Primary Examiner
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JPW
July 31, 2003